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REMARKS

Request for Waiver of Restriction Requirement

Although Applicants have elected Group V as required by the Examiner, Applicants respectfully request the Examiner waive the restriction (as to all Groups) because the examination of these groups in one application is reasonable, would not unduly burden the Examiner, and will aid Applicants in protecting their intellectual property:

To further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR §1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.... It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.

MPEP § 803.04 [Emphasis Added].

Groups I-IV are directed toward a method of treating an HIV infection through the administration of a peptide. The peptides to be delivered comprise an amino acid selected from (a) KPV; (b) MEHFRWG; (c) HFRWGKPV; and (d) SYSMEHFRWGKPV. Groups V-VIII are directed toward a method of treating secondary infections, also through the administration of a peptide. Here as well, the peptides to be delivered comprise an amino acid selected from (a) KPV; (b) MEHFRWG; (c) HFRWGKPV; and (d) SYSMEHFRWGKPV. Groups IX-XII are directed toward a method of treating inflammation, again through the administration of a peptide. And again, the peptides to be delivered comprise an amino acid selected from (a) KPV; (b) MEHFRWG; (c) HFRWGKPV; and (d) SYSMEHFRWGKPV. Hence, the peptides to be

delivered are the same for each group. Each peptide comprises an amino acid sequence derived from α MSH. Therefore, examination of these three groups together is reasonable and not unduly burdensome because the amino acid sequences are related.

The peptide sequences KPV, MEHFRWG; and HFRWGKPV are all part of the peptide sequence SYSMEHFRWGKPV, which codes for α MSH. See page 7, line 21 to page 8, line 1. Hence, their mode of action will be intrinsically related to one another. See page 16, lines 17-18. Further, these peptides may be delivered separately or in conjunction with one another. See page 4, lines 12-14. In addition, the concentrations and modes of administration are the same for all 12 groups. See page 33, line 14-19. Because of this inter-relatedness, it is reasonable to examine the claims in Groups I-XII together.

As provided by the MPEP § 803.04, "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." Groups I-XII only relate to four sequences. Because all of the sequences are derived from α MSH and therefore, not patentably distinct, Applicants respectfully submit that examination of these groups together is reasonable and will not unduly burden the Examiner.

Applicants understand that MPEP §803.04 expressly provided a waiver to examination of multiple nucleotide sequences in one application, but did not explicitly address amino acid sequence. However, given the relationship between the nucleic acid sequence and amino acid sequences, the rationale for waiving the restriction requirement for nucleic acid sequences reasonably applies to claims having amino acid sequence limitations.

CONCLUSION

Based on MPEP § 803.04 that allows for a reasonable number of sequences to be examined in one application, Applicants respectfully request the Examiner to waive the restriction requirement as to all Groups and allow them to be examined together.

Applicants hereby request a one-month extension of time. Please charge the appropriate amount to Deposit Account **12-2475**. If this fee is incorrect, the Commissioner is hereby authorized to charge or credit our Deposit Account of said amount.

Respectfully submitted,

LYON & LYON LLP

Dated: _____

8/17/01

By: _____

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